

Pharma & Healthcare Update

December 03, 2013

ADDITIONAL COMPLIANCES FOR CLINICAL TRIALS PRESCRIBED

- Audio - video recording of informed consent process in clinical trials has been made mandatory.
- A new formula for deciding compensation for clinical trial related death has been published.
- Financial interests of investigators are required to be disclosed at the time of applying for permission to conduct clinical trials in India.

1. AUDIO - VIDEO RECORDING OF INFORMED CONSENT MANDATORY

The Drugs Controller General of India ("DCGI") has issued an office Order making audio - video recording of informed consent mandatory for new subject enrolments in all clinical trials in India. The Order is effective from November 19, 2013.

Schedule Y of the Drug and Cosmetics Rules, 1945 ("Rules") already provides that the Investigator is required to provide information about the study verbally in a language that is non-technical and that can be understood by the study subject. This requirement is in addition to providing a patient information sheet for the same purpose. Further, where a subject is unable to give informed consent (e.g., an unconscious person or a minor or those suffering from severe mental illness or disability), it is required to be obtained from a legally accepted representative on behalf of such subject. Where the subject or his/her legally acceptable representative is unable to read/write, an impartial witness is required to be present during the entire informed consent process.

The Order mandates that audio – video recording of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent, be done while adhering to the principles of confidentiality and in addition to obtaining the written informed consent of the subject. The Order further mandates that all such audio - video recording be preserved.

The Order, currently, appears to be applicable to new subject enrolments in clinical trials of 'new drugs' only (as it only talks about new drugs as are regulated under the provisions of the Rules). The new requirement is likely to create procedural inconvenience for Investigators apart from increasing the cost of conducting clinical trials. Moreover, since the Order does not specify any details on preservation of the records, it is unclear on what the minimum duration is for which the recordings have to be preserved. The Sponsors will need to ensure these requirements are captured appropriately in their contracts with Contract Research Organizations ("CROs") / Institutions / Investigators in India. In addition, since collection and storage of sensitive personal data or information in the audio-visual recording will be in electronic form, requirements for compliance with the Indian data protection laws, i.e., the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 will be a necessity.

2. FORMULA FOR COMPENSATION PUBLISHED

An Expert Committee ("Committee") has published a formula that is intended to be relied on by the authorities for recommending the compensation payable in case of clinical trial related death ("Formula"). The committee is a statutory body constituted by the DCGI to provide recommendations to the DCGI on the amount of compensation to be awarded in case of a clinical trial related death. Readers may recollect there was a formula for determining the quantum of compensation payable to clinical trial subjects that was proposed by the Central Drugs Standard Control Organization sometime in August 2012. The relevant alert, in this respect, circulated by Nishith Desai Associates can be found [here](#). This proposal was not, eventually, implemented as the amounts arrived at using the formula appeared vague and unreasonable. Pursuant to stakeholder comments and several deliberations amongst the industry players and the Committee, the Formula has now been published. Though, it may be noted that the Formula is limited to cases of death only and is not applicable to injury related cases.

The Committee has decided to employ the following factors while calculating compensation:

1. **Age:** Older the study subject, lesser the compensation. Each age is assigned a unique numerical factor ranging from 228.54 (for age 16 and less) to 99.37 (for age 65 and more). A table containing the age and corresponding factor has been annexed to the official publication.
2. **Risk:** Lesser the risk to the subject prior to participation, higher the compensation. Depending upon the seriousness and severity of the disease, presence of co-morbidity and duration of the disease of the subject at the time of his/her enrolment in the clinical trial, a risk factor will be assigned to the subject ranging from 0.5 (terminally ill patient) to 4.0 (healthy volunteer with no risk).
3. **Base:** The Committee decided to introduce a base factor of INR 800,000 (approximately USD 13,300) with the

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intention that base factor be the minimum amount receivable as compensation. The base factor is to be revised periodically against inflation whenever the minimum wage offered by the government is revised to adjust against inflation.

The formula for calculation of compensation is:

$$B \times F \times R / 99.37$$

Where,

B = Base factor

F = Age factor

R = Risk factor

99.37 = Age factor corresponding to the age category - 65 or more.

Based on this formula, the compensation payable in case of clinical trial related death will vary from a minimum of INR 400,000 (approximately USD 6600) to a maximum of INR 7,360,000 (approximately USD 122,000). The Committee has, separately, also provided that a fixed compensation of INR 200,000 (approximately USD 3300) will be paid for clinical trial related death of a subject whose expected mortality is 90% or more within 30 days.

The publication provides that the Formula be treated as 'provisionally final'. It is unclear, at this point, what is implied by this term, however, it does appear that for the purpose of determining clinical trial death related compensation, this Formula may be relied on by the drug regulators even though it is not officially implemented just yet. Moreover, it remains to be seen if the past years' compensation related cases will be determined by the drug regulators based on the Formula.

3. INVESTIGATORS TO DISCLOSE FINANCIAL INTEREST

The DCGI issued an office order on August 30, 2013 requesting all Sponsors or its representatives to furnish "details of the contract entered into by the Sponsor with the Investigator / Institutions with respect to financial support, fees, honorarium, and payment in kind etc. to be paid to the Investigator" at the time of making an application for permission to conduct clinical trials in India.

Though the intent behind this move may be to, perhaps, bring transparency within the system, it is likely to bring about delays and additional procedural difficulties in the entire process of obtaining permission to conduct clinical trials in India.

The implementation of the order has posed a big challenge for the industry. A Sponsor / CRO, typically, enters into a contract with the Institution (and Investigator) after it receives permission to conduct clinical trial in India. That way, it leads to a more efficient arrangement to avoid loss of time and any additional delays. If it was the other way round (as it now appears to be the case), that is if the contract was entered into before it received permission, and the permission did not come through, or came with prohibitory conditions, then it would result in loss of precious time, negotiations and paperwork for the Sponsor. Hence, the industry is now faced with a dilemma where it appears that it is now required to establish a contractual relationship before applying for permission to conduct a clinical trial.

Since there are no standards / guidelines provided on what financial terms of a contract between the Sponsor and Investigator / CRO are to be deemed appropriate, it is difficult to ascertain how each contract will be dealt with and interpreted by the DCGI, and which could continue to be a cause for concern for the Sponsors / CROs / Investigators.

– **Anay Shukla & Khushboo Baxi**

You can direct your queries or comments to the authors

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